Cardium Therapeutics, Inc.
Form 10-K
April 05, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012

001-33635

(Commission file number)

CARDIUM THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**27-0075787**
(State of incorporation)	**(IRS Employer Identification No.)**
12255 El Camino Real, Suite 250	
San Diego, California 92130	**(858) 436-1000**
(Address of principal executive offices)	**(Registrant s telephone number)**

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	**Name of exchange on which registered**
Common Stock, $0.0001 par value per share	**NYSE MKT**

Securities registered under Section 12(g) of the Exchange Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ¨ Yes x No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. ¨ Yes x No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes ¨ No

Indicate by checkmark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant for Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes ¨ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ¨	Accelerated filer ¨	Non-accelerated filer ¨	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ¨ Yes x No

The aggregate market value of common equity held by non-affiliates, computed on the basis of the closing sale price for the common stock as reported on the NYSE MKT on June 30, 2012, was $24.6 million. Shares of common stock held by executive officers, directors and by persons who own 10% or more of the outstanding common stock of the registrant have been excluded for purposes of the foregoing calculation in that such persons may be deemed to be affiliates. This does not reflect a determination that such persons are affiliates for any other purpose.

As of March 20, 2013, 129,562,061 shares of Cardium s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K incorporates by reference portions of Cardium s definitive proxy statement for its Annual Meeting of Stockholders to be filed on or before April 30, 2013.

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Unless the context requires otherwise, all references in this report to the Company, Cardium, we, our, and us refer to Cardium Therapeutics, and, as applicable, its wholly owned subsidiaries Post-Hypothermia Corporation (formerly, InnerCool Therapies, Inc.), Tissue Repair Company and To Go Brands, Inc.

SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

Certain statements in this report, including information incorporated by reference, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934, and the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect current views about future events and financial performance based on certain assumptions. They include opinions, forecasts, intentions, plans, goals, projections, guidance, expectations, beliefs or other statements that are not statements of historical fact. Words such as may, will, should, could, would, expects, plans, believes, anticipates, intends, estimates, ap projects, or the negative or other variation of such words, and similar expressions may identify a statement as a forward-looking statement. Any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results and the development of our products, are forward-looking statements. Forward-looking statements in this report may include statements about:

- our ability to fund operations and business plans, and the timing of any funding or corporate development transactions we may pursue;
- planned development pathways and potential commercialization activities or opportunities;
- the timing, conduct and outcome of discussions with regulatory agencies, regulatory submissions and clinical trials, including the timing for completion of clinical studies;
- our ability to increase revenues, raise sufficient financing and to otherwise maintain the listing of our common stock on a national exchange;
- our beliefs and opinions about the safety and efficacy of our products and product candidates and the anticipated results of our clinical studies and trials;
- our ability to enter into acceptable relationships with one or more contract manufacturers or other service providers on which we may depend, and the ability of such contract manufacturers or other service providers to manufacture biologics, devices, nutraceuticals or other key products or components, or to provide other services, of an acceptable quality on a timely and cost-effective basis;
- our ability to enter into acceptable relationships with one or more development or commercialization partners to advance the commercialization of new products and product candidates and the timing of any product launches;
- our growth, expansion and acquisition strategies, the success of such strategies, and the benefits we believe can be derived from such strategies;
- our ability to pursue and effectively develop new product opportunities and acquisitions and to obtain value from such product opportunities and acquisitions;

our intellectual property rights and those of others, including actual or potential competitors;

the outcome of litigation matters;

the anticipated activities of our personnel, consultants and collaborators;

expectations concerning our operations outside the United States;

current and future economic and political conditions;

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overall industry and market performance;

the impact of new accounting pronouncements;

management s goals and plans for future operations; and

other assumptions described in this report underlying or relating to any forward-looking statements.

The forward-looking statements in this report speak only as of the date of this report and caution should be taken not to place undue reliance on any such forward-looking statements. Forward-looking statements are subject to certain events, risks, and uncertainties that may be outside of our control. When considering forward-looking statements, you should carefully review the risks, uncertainties and other cautionary statements in this report as they identify certain important factors that could cause actual results to differ materially from those expressed in or implied by the forward-looking statements. These factors include, among others, the risks described under Item 1A and elsewhere in this report, as well as in other reports and documents we file with the United States Securities and Exchange Commission (the SEC).

PART I

ITEM 1. BUSINESS

Overview

Cardium is an asset-based health sciences and regenerative medicine company focused on the acquisition and strategic development of innovative products and businesses having the potential to address significant unmet medical needs, and definable pathways to commercialization, partnering or other monetization following the achievement of corresponding development objectives. Our current portfolio includes Cardium Biologics, Tissue Repair Company and To Go Brands, Inc., companies primarily focused on the development of innovative therapeutic products for cardiovascular indications, wound healing and nutraceutical supplements, respectively. As a development stage company, we have yet to generate positive cash flows from operations and are essentially dependent on debt and equity funding and partnering or other monetization transactions to finance our operations.

Cardium Therapeutics, Inc. was organized in Delaware in December 2003.

Significant portfolio transactions since that date include the following:

In October 2005, we acquired a portfolio of biologic growth factors and related delivery techniques from the Schering AG Group (now part of Bayer AG) for potential use in treating ischemic and other cardiovascular conditions, including Generx®, a product candidate being developed for patients with chronic myocardial ischemia (insufficient blood flow within the heart muscle) due to coronary heart disease.

In March 2006, we acquired the technologies and products of InnerCool Therapies, Inc., a medical technology company in the emerging field of therapeutic hypothermia, or patient temperature modulation, whose systems and products are designed to rapidly and controllably cool the body to reduce cell death and damage following acute ischemic events such as cardiac arrest and stroke, and to potentially lessen or prevent associated injuries such as adverse neurologic outcomes.

In August 2006, we acquired rights to assets and technologies of Tissue Repair Company, a company focused on the development of growth factor therapeutics for the potential treatment of tissue wounds such as chronic diabetic wounds, and whose product candidate, Excellagen® is FDA-cleared as a single administration therapeutic for the treatment of non-healing, neuropathic diabetic foot ulcers and other dermal wounds.

On July 24, 2009, we sold all of the assets and liabilities of our InnerCool Therapies business to Philips Electronics North America Corporation for $11.25 million, as well as the transfer of approximately $1.5 million in trade payables.

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In November 2010, we announced the launch of our MedPodium® healthy lifestyle product platform and web boutique. MedPodium is a portfolio of premium science-based, easy to use medicinals, neurologics, metabolics, nutraceuticals and aesthetics intended to promote and manage personal health. In addition, Cardium has developed the MedPodium Nutra-Apps® product line (Neo-Energy®, Neo-Carb Bloc® and Neo-Chill) for distribution in convenience stores and other channels.

In March 2012, we introduced our FDA-cleared Excellagen® professional-use wound care product for the treatment of diabetic foot ulcers and other dermal wounds, and entered into a logistics and cold chain services agreement with Smith Medical Partners, a subsidiary of H. D. Smith.

In March 2012, we initiated our Generx® ASPIRE Phase 3 registration study involving approximately 100 patients at up to nine leading medical centers in Russia

On September 28, 2012 we acquired substantially all of the assets, business and product portfolio of privately-held To Go Brands, Inc. To Go Brands develops, markets and sells a portfolio of over 25 products, including nutraceutical powder mixes, supplements and chews to support healthy lifestyles. The product line includes antioxidant-rich drink mixes in convenient stick packs that are designed to pour directly into a water bottle, as well as mix packages for home use and capsule-based dietary supplements, including Trim Green Coffee Bean, which supports healthy weight loss. These products are sold through food, drug and mass channels at retailers including Whole Foods, CVS, Kroger, GNC, Jewel-Osco, Ralph s Supermarkets, Meijer, and the Vitamin Shoppe and from the company s web-based store.

In January 2013, we announced the planned partner-enabled clinical development of Genedexa (previously referred to as the Excellarate product candidate and an asset of Tissue Repair Company), a DNA-based Phase 2b/3 product candidate initially for the treatment of chronic, non-healing diabetic foot ulcers and representing the first product extension from our FDA-cleared Excellagen® technology platform.

In January 2013, we announced our in-house product development of, LifeAgain , a partner-enabled medical analytics and e-commerce platform of algorithms and medical-based programs that were developed by our researchers to support a strategically partnered commercialization of specialized survivable risk life insurance underwritings for cancer patients and patients with chronic medical diseases, based on the improvement of early diagnosis and new chronic treatments and curative medical therapies.

Our business model is designed to create multiple opportunities for success while avoiding reliance on any single technology platform or product type, and to leverage our skills in late-stage product development in order to bridge the critical gap between promising new technologies and product opportunities that are ready for commercialization. Consistent with our long-term strategy, we intend to consider various corporate development transactions designed to place our product candidates into larger organizations or with partners having existing commercialization, sales and marketing resources, and a need for innovative products. Such transactions could involve the sale, partnering or other monetization of particular product opportunities or businesses. In parallel, as our businesses are advanced and corresponding valuations established, we plan to pursue new product opportunities and acquisitions with strong value enhancement potential.

Cardium Biologics

Generx

Generx (alferminogene tadenovec/CardioNovo®) is a DNA-based angiogenic therapy being developed for the potential treatment of myocardial ischemia due to advanced coronary artery disease. Generx is designed to stimulate and promote the growth of supplemental collateral vessels to enhance myocardial blood flow (perfusion) following a one-time intracoronary administration from a standard cardiac infusion catheter in patients who have insufficient blood flow due to atherosclerotic plaque build-up in the coronary arteries.

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In March 2012, we initiated the Generx ASPIRE Phase 3 / registration study involving approximately 100 patients at up to nine leading medical centers in Russia, and using SPECT imaging as a key clinical endpoint. If the trial is successful, we hope to gain approval to sell Generx in Russia and in the Commonwealth of Independent States. We also believe that having additional clinical evidence confirming the safety and effectiveness of Generx for improving coronary collateral circulation in men and women with severe coronary artery disease could potentially be used to optimize and broaden commercial development pathways in the U.S. and other industrialized countries.

Generx is also cleared by the FDA for a Phase 3 clinical study in the U.S. for women with late stage coronary artery disease who are unresponsive to traditional drug therapy and are not appropriate candidates for mechanical revascularization (angioplasty/stents or by-pass surgery). However, in view of published results from an independent 10-year study among men and women with chronic coronary heart disease showing that improved collateral circulation was associated with substantially lower cardiac mortality (Circulation 116:975-983, 2007), and prior studies showing that a one-time infusion of Generx has the potential to achieve improved coronary collateral circulation in both men and women at levels approximately equivalent to bypass surgery as measured by SPECT imaging (J Am Coll Cardiology 42(8):1339-1347, 2003), we believe that Generx could potentially be developed as a cost effective front-line therapy for patients with coronary artery disease in the large markets of newly-industrializing countries who often do not have access to costly procedures such as bypass surgery.

Incidence of Cardiovascular Disease

According to the Centers for Disease Control and Prevention, heart disease is the leading cause of death for both men and women in the U.S.

Coronary heart disease costs the U.S. an estimated $108.9 billion each year, which includes the cost of healthcare services, medications, and lost productivity.

According to the Federal Research Institute for Health Organization and Informatics of the Russian Ministry of Health, cardiovascular disease affects over 30 million people in the Russian Federation. An estimated 3.5 million patients were newly diagnosed with the disease in 2011.

In 2012, approximately one million deaths were attributable to cardiovascular disease in the Russian Federation.

Current Treatment Approaches for Coronary Artery Disease

Current treatments of coronary artery disease include drugs such as ACE inhibitors, beta-blockers, calcium channel blockers, nitrates, such as nitroglycerin, statins, and Ranexar® (Gilead Sciences) known as Ranolazine for the treatment of angina). Surgical and mechanical interventions for the treatment advanced coronary disease include angioplasty and stents (percutaneous coronary interventions), coronary artery bypass surgery (CABG), and robot-assisted coronary artery bypass).

We believe that treatment with Generx may serve as a lower cost alternative to traditional surgery and stents.

Tissue Repair Company

Excellagen®

On October 3, 2011, our Tissue Repair Company subsidiary received a 510(k) premarket notification from the U.S. Food and Drug Administration (FDA) for its Excellagen® highly refined fibrillar collagen-based topical gel for the management of diabetic foot ulcers and other dermal wounds. Our 510(k) clearance covers Excellagen s use by healthcare professions for topical application to dermal wounds, which include diabetic ulcers, pressure ulcers, venous ulcers, tunneled/undermined wounds, surgical and trauma wounds, second degree burns, and other types of wounds. Following FDA approval, in March 2012 we entered into a logistics and cold

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chain services agreement with Smith Medical Partners, a subsidiary of H. D. Smith. We began initial sales of our Excellagen product® in 2012.

In addition to its application for dermal wounds, Excellagen® has been engineered to serve as a delivery platform enabling multiple device and therapeutic product extensions to include antimicrobials, small molecule drugs, peptides, conditioned cell media, stem cells and DNA-based biologic products. We plan to develop extensions for our Excellagen platform internally and with potential development partners.

Incidence of Chronic Wounds

Over 18 million chronic wounds are treated annually worldwide, with 6 million patients developing chronic wounds in the U.S. The costs of chronic wounds to the U.S. healthcare system are estimated to be $20 billion annually.

Approximately 2 million patients suffer from pressure wounds, 1.2 million from diabetic foot ulcers and up to 2 million patients seek treatment for venous ulcers annually.

An estimated 347 million people worldwide have diabetes. Diabetes affects over 25 million people in the U.S., representing over 8 percent of the population. According to the American Diabetes Association, the costs associated with diabetes in 2012 in the U.S. totaled $245 billion, including $175 billion in direct medical costs and $69 billion in reduced productivity.

Approximately 15-25% of diabetic patients will develop foot ulcers and the recurrence rate of these patients developing new ulcers are 34%, 61%, and 70% after one, three and five years of follow up, respectively. Eventually 15-24% of these patients will require amputation.

Current Treatment Approaches for Chronic Wounds

There are several treatment modalities currently used for chronic ulcers in diabetic patients and other dermal wounds, including topical dressings, dermal substitutes, negative pressure wound therapies, and debridement with offloading. Regranex® Gel (becaplermin), which is currently marketed by Healthpoint Biotherapeutics, now an operating unit of Smith & Nephew, is considered to be the only FDA-approved prescription medicine to treat such wounds. Regranex® is a recombinant human platelet-derived growth factor protein that is used as an adjunct with other current treatment modalities described above to treat lower extremity diabetic neuropathic ulcers.

In addition, human dermal substitute products, including Apligraf® (Organogenesis Inc.), Dermagraft® (Shire Pharmaceuticals), and Graftjacket® Regenerative Tissue Matrix (KCI USA, Inc.) advanced wound care products are currently being used by physicians in the treatment of chronic diabetic foot ulcers and other dermal wounds. Additional wound care treatments include negative pressure, ultra-sound, and transdermal oxygen wound therapies, such as the MIST ultra-sound therapy (Celleration, Inc.), negative pressure systems (Kinetic Concepts Inc. (KCI) and Smith & Nephew), and EPIFLO® Transdermal Oxygen Therapy (Ogenix). Additionally, in certain markets, Excellagen competes with other syringe-based wound care products which include Inegra™ Wound Matrix, marketed by Integra LifeSciences and Graftjacket® Xpress marketed by KCI.

To Go Brands

On September 28, 2012, our Medpodium Health Products subsidiary acquired substantially all of the assets, business and product portfolio of privately-held To Go Brands, Inc., and subsequently changed its corporate name to To Go Brands, Inc. To Go Brands develops, markets and sells a portfolio of over 25 products, including nutraceutical powder mixes, supplements and chews to support healthy lifestyles at over 10,000 food, drug and mass retailers. We have consolidated our nutraceutical initiative, which includes To Go Brands, the MedPodium Nutra-Apps® product line as well as our strategic investment in SourceOne Global Partners, a leading supplier of science-based ingredients and proprietary formulas, into a single operating entity.

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A majority of the revenues we generated in 2012 were derived from sales of our nutritional supplements, including sales of To Go Brands products following the acquisition on September 28, 2012. We anticipate that sales of nutraceutical products will continue to comprise the majority of our revenues over the next 12 months while we advance the commercialization of Excellagen and continue development of our other product candidates.

We plan to (1) realign the To Go Brands products into three segments: Go Active! Go Health! And Go Trim!; (2) increase online customer acquisition and retention via super affiliate programs and social media-based coupon offerings; (3) add new product offerings; and (4) further expand U.S. retail distribution and establish distributors to leverage on the success of To Go Brands Trim Energy Green Coffee Bean dietary supplement featuring Svetol®.

Nutraceutical Supplement Market

According to the Nutrition Business Journal, the U.S. supplement industry grew 7% in 2011 to reach $30 billion in sales.

Sales by product included meal replacement (10%), specialty (10%), vitamins (34%), herbs and botanicals (17%), sports nutrition (12%), and minerals (8%).

Large pharmaceutical companies have entered the nutraceutical market and are diversifying their product lines with dietary-supplement products with large market potential and without the extensive regulatory hurdles. In February 2012, Pfizer acquired privately-held Alacer Corp., the maker and distributor of Emergen-C®, a vitamin C product. Schiff Nutrition International recently purchased Airborne, Inc., a leading provider of immune support products, and in October 2012, Bayer HealthCare announced its acquisition of Schiff Nutritional International.

Business Strategy

We operate in an industry that is characterized by significant upfront capital costs, with the potential for significant returns for a successful product. Conducting the costly and time consuming research, pre-clinical and clinical testing necessary to obtain regulatory approvals and bring our products to market will require a commitment of substantial funds. Given the limited nature of our revenues and the high costs we must incur to develop our product candidates, we have yet to generate positive cash flows or income from operations and do not anticipate doing so in the foreseeable future. As a result, we have been dependent on debt and equity funding to finance our operations. During 2012, we raised net proceeds of $6.4 million through the completion of a registered direct equity financing with three institutional and accredited investors of 17.9 million shares of Cardium common stock priced at $0.28 per share with no warrant coverage for net proceeds of approximately $4.5 million and through the sale of 5.2 million shares of common stock under at-the-market transactions for net proceeds of $1.9 million.

Building on our core products and product candidates, our strategic goal is to develop a portfolio of medical products at various stages of development and secure additional financial resources to commercialize these products in a timely and effective manner. Our business strategy includes the establishment of research collaborations to support and supplement our discovery, pre-clinical and clinical research and development phases of the product commercialization cycle, as well as the implementation of long-term strategic partnerships with one or more commercialization partners to support clinical trials and product commercialization activities, including product manufacturing, marketing and distribution.

Consistent with our long-term strategy, we intend to consider various corporate development transactions designed to place our product candidates into larger organizations or with partners having existing commercialization, sales and marketing resources, and a need for innovative products. Such transactions could

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involve the sale, partnering or other monetization of particular product opportunities or businesses. In parallel, as our businesses are advanced and corresponding valuations established, we plan to pursue new product opportunities and acquisitions with strong value enhancement potential.

The key elements of our current business strategy are to:

- advance our clinical study for Generx®, the APSIRE Phase 3 registration clinical study, in Russia;
- commercialize our Excellagen® wound care product and develop new product extensions based on our custom formulated collagen product platform for additional wound healing applications;
- grow our recently-acquired To Go Brands® nutraceutical supplement business by introducing additional product line extensions and further expanding U.S. retail distribution and establishing distributor relationships.;
- plan to initiate a partner-enabled clinical development of Genedexa (previously referred to as the Excellarate product candidate), a DNA-based Phase 2b/3 product candidate initially for the treatment of chronic, non-healing diabetic foot ulcers and representing the first product extension from our FDA-cleared Excellagen® technology platform;
- continue development of our new in-house partner-enabled product, LifeAgain , a medical analytics and e-commerce platform of algorithms and medical-based social media programs that were developed by Cardium researchers to support a strategically partnered commercialization of specialized survivable risk life insurance underwritings for cancer patients and patients with chronic medical diseases, based on the improvement of early diagnosis and new chronic treatments and curative medical therapies; and
- continue to review potential acquisitions of other businesses, product opportunities and technologies on favorable economic terms consistent with our long-term business strategy.

Government Regulation

New drugs, biologics, devices, and nutraceuticals, are subject to extensive regulation in the United States under the federal Food, Drug, and Cosmetic Act. In addition, biologics are also regulated under the Public Health Service Act. We believe that the pharmaceutical products we are attempting to develop will be regulated either as biological products or as new drugs. Both statutes and their corresponding regulations govern, among other things, the testing, manufacturing, distribution, safety, efficacy, labeling, storage, record keeping, advertising and other promotional practices involving biologics or new drugs. FDA approval or other clearances must be obtained before clinical testing, and before manufacturing and marketing, of biologics and drugs. Obtaining FDA approval has historically been a costly and time-consuming process. Different regulatory regimes are applicable in other major markets.

In addition, any gene therapy and other DNA-based products we develop will require regulatory approvals before human trials and additional regulatory approvals before marketing. New biologics are subject to extensive regulation by the FDA and the Center for Biological Evaluation and Research and comparable agencies in other countries. Currently, each human-study protocol is reviewed by the FDA and, in some instances, the NIH, on a case-by-case basis. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols.

To commercialize our product candidates, we must sponsor and file an investigational new drug (IND) application and be responsible for initiating and overseeing the human studies to demonstrate the safety and efficacy and, for a biologic product, the potency, which are necessary to obtain FDA approval of any such products. For our newly sponsored investigational new drug applications, we will be required to select qualified investigators (usually physicians within medical institutions) to supervise the administration of the products, and we will be required to ensure that the investigations are conducted and monitored in accordance with FDA regulations and the general investigational plan and protocols contained in the IND application.

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The FDA receives reports on the progress of each phase of testing, and it may require the modification, suspension, or termination of trials if an unwarranted risk is present to patients. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. The IND application process can thus result in substantial delay and expense. Human gene therapy products, a primary area in which we are seeking to develop products, are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials to establish the safety, efficacy and potency of human gene therapy products, or that the data generated in these studies will be acceptable to the FDA to support marketing approval.

After the completion of trials of a new drug or biologic product, FDA marketing approval must be obtained. If the product is regulated as a biologic, the Center for Biological Evaluation and Research will require the submission and approval, depending on the type of biologic, of either a biologic license application or a product license application and a license application before commercial marketing of the biologic. If the product is classified as a new drug, we must file a new drug application with the Center for Drug Evaluation and Research and receive approval before commercial marketing of the drug. The new drug application or biologic license applications must include results of product development, laboratory, animal and human studies, and manufacturing information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the new drug application or biologic license applications for filing and, even if filed, that any approval will be granted on a timely basis, if at all. In the past, new drug applications and biologic license applications submitted to the FDA have taken, on average, one to two years to receive approval after submission of all test data. If questions arise during the FDA review process, approval can take more than two years.

Notwithstanding the submission of relevant data, the FDA may ultimately decide that the new drug application or biologic license application does not satisfy its regulatory criteria for approval and may require additional studies. In addition, the FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and effectiveness. Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to compliance with current good manufacturing practices (GMPs), reporting of adverse effects, advertising, promotion and marketing. Discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

Ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we or our suppliers may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing any such products.

The approval and/or clearance for marketing of medical devices, such as Excellagen and potentially other product candidates of our Tissue Repair Company subsidiary, are also subject to extensive controls by health regulatory and other authorities. Although some devices can be cleared for marketing pursuant to a procedure referred to as an FDA 501(k) clearance, other devices and/or indications may require additional clinical studies and may be subject to even more extensive regulatory and other controls.

Nutraceuticals, dietary supplements and other products intended for human consumption, such as those included or to be included in our To Go Brands and MedPodium product portfolios, are also subject to numerous rules and regulations promulgated by the FDA and other food and health regulatory authorities, including regulations governing the sourcing, manufacture, labeling, handling, storage, marketing and use of such products.

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the

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Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

We are also subject to a variety of other regulations in the United States, including those relating to bioterrorism, taxes, labor and employment, import and export, and intellectual property.

To the extent we have operations outside the United States, any such operations would be similarly regulated by various agencies and entities in the countries in which we operate. The regulations of these countries may conflict with those in the United States and may vary from country to country. In markets outside the United States, we may be required to obtain approvals, licenses or certifications from a country s ministry of health or comparable agency before we begin operations or the marketing of products in that country. Approvals or licenses may be conditioned or unavailable for certain products. These regulations may limit our ability to enter certain markets outside the United States.

Competition

The pharmaceutical, biotechnology, medical device and nutraceutical industries are intensely competitive. Our products and any product candidates developed by us would compete with existing drugs, therapies, devices or procedures and with others under development. There are many pharmaceutical, biotechnology and medical device companies, public and private universities and research organizations actively engaged in research and development of products for the treatment of cardiovascular and related diseases, and/or products for the healing of chronic wounds, and many nutraceutical companies with existing and rapidly evolving product lines. Many of these organizations have financial, technical, research, clinical, manufacturing and marketing resources that are greater than ours. If a competing company develops or acquires rights to a more efficient, more effective, or safer competitive approach for treatment of the same or similar diseases or conditions we have targeted, or one that offers significantly lower costs of treatment, our business, financial condition and results of operations could be materially adversely affected.

We are aware of products currently under development by competitors targeting the same or similar cardiovascular and vascular diseases as our Generx product. These include biologic treatments using forms of genes and therapeutic proteins. For example, CardioVascular BioTherapeutics is developing injectable and topical forms of FGF-1 for the potential treatment of cardiovascular diseases. We will also face competition from entities using other traditional methods, including new drugs and mechanical therapies, to treat cardiovascular and vascular disease.

In the areas of tissue repair and wound healing, as being developed by our Tissue Repair subsidiary, there are a number of approaches being employed, including other collagen-based products, living skin equivalents, negative pressure wound therapy devices and other devices, and biologics and small molecule drugs designed to promote repair and healing.

Nutraceutical businesses and other providers of healthy lifestyle products represent a very large and intensely competitive industry. Many of these organizations have financial, technical, product development, manufacturing and marketing resources that are far greater than ours or our collaborators, and may offer established and new products for addressing the same or similar conditions that could be safer, more effective and/or less costly than ours, or could be marketed and distributed more effectively and efficiently.

We believe that the most significant competitive factor in the field of new therapeutics and devices is the effectiveness of a product candidate, as well as its relative safety and cost as compared to other products, product candidates or approaches that may be useful for treating a particular disease condition.

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We believe that our product development programs will be subject to significant competition from companies using alternative technologies, some of which are described above, as well as to increasing competition from companies that develop and apply technologies similar to ours. Other companies may succeed in developing products earlier than we do, obtaining approvals for these products from the FDA more rapidly than we do or developing products that are safer, more effective or less expensive than those under development or proposed to be developed by us. We cannot assure you that research and development by others will not render our technology or product candidates obsolete or non-competitive or result in treatments superior to any product candidate developed by us, or that any product candidate developed by us will be preferred to any existing or newly developed technologies.

Manufacturing Strategy

To leverage our experience and available financial resources, we do not plan to develop company-owned and operated manufacturing facilities. We plan to outsource all product manufacturing to one or more contract manufacturers of clinical drug products that operate manufacturing facilities in compliance with current Good Manufacturing Practices. We may also seek to refine the current manufacturing process and final product formulation to achieve improvements in storage temperatures and the like.

The FDA has established guidelines and standards for the development and commercialization of molecular and gene-based drug products i.e.: *Guidance for Industry CMC for Human Gene Therapy INDs November 2004, Sterile Drug Products Produced by Aseptic Processing September 2004, Human Somatic Cell Therapy and Gene Therapy March 1998, PTC in the Characterization of Cell Lines Used to Produce Biologicals July 1993.* These industry guidelines, among others, provide essential oversight with regard to process methodologies, product formulations and quality control standards to ensure the safety, efficacy and quality of these drug products.

Marketing and Sales

Our marketing and sales strategy varies by product line. Our product candidates, such as Generx must undergo clinical trials before any marketing and sales can begin. If we should obtain marketing approvals, we expect to engage in marketing and sales efforts through or in collaboration with a partner that specializes in commercialization, marketing and sales of drugs and therapeutics.

For our Excellagen® wound care product, we expect to engage in sales principally through or in collaboration with a sales and distribution and strategic partners. In March 2012 we entered into a logistics and cold chain services agreement with Smith Medical Partners, a subsidiary of H. D. Smith. We also entered into sales and distribution agreements with Academy Medical to market, sell and distribute Excellagen to U.S. government medical providers, including Veterans Administration and military hospitals.

For our nutraceutical supplement business, To Go Brands is engaged in sales through food and drug retailers, distributors and our own on-line store.

Licensing and Intellectual Property

Our overall business strategy is principally focused on the acquisition and development of a portfolio of product opportunities which involves a variety of intellectual property rights, including patent prosecution and inbound and outbound licensing transactions.

As part of our acquisition of a portfolio of cardiovascular growth factor therapeutic assets pursuant to a Technology Transfer Agreement entered into between Cardium and the Schering AG Group (now part of Bayer AG), we acquired from Schering a portfolio of methods and compositions directed at the treatment of cardiovascular diseases, including Generx. In connection with that portfolio we acquired the rights to certain patents owned by the

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University of California, New York University and Yale University, which would require us to pay royalties on products developed on the basis of those patents. Information related to our purchase from Schering AG Group is provided under Notes to Consolidated Financial Statements, Note 8 Commitments and Contingencies. Our patent portfolio includes allowed and issued patents covering our gene therapy approach both in Europe and in the United States. We have additional patents and patent applications directed to its methods of cardiovascular gene therapy in the U.S., Europe, Russia and elsewhere, and we recently filed new patent applications directed to certain improved techniques for the treatment of heart disease that are currently the subject of Cardium s ASPIRE study in Russia.

In August 2006, we acquired the rights to various technologies and products now part of our Tissue Repair Company subsidiary. In connection with that acquisition we acquired the rights to use certain patented technology related to a growth factor DNA in exchange for royalty payments. Our Excellagen product product does not contain the growth factor DNA, and we do not have any ongoing material commitments or royalty obligations with respect to the new Excellagen product candidate under our prior transaction in which we acquired substantially all of the assets of the Tissue Repair Company. We are looking to develop extensions to that platform, including the patented growth factor DNA which would require the payment of royalties if a product is ultimately developed and approved.

In connection with our acquisition of To Go Brands, Inc. we acquired certain proprietary formulations, trade names, and customer lists. We have also licensed rights from third party manufacturers to develop exclusive formulations for our nutraceutical supplement product lines.

We expect to continue evaluations of the safety, efficacy and possible commercialization of our product candidates and technologies as they advance in development. On the basis of such evaluations, we may alter our current research and development programs, clinical studies, partnering or other development or commercialization activities. Accordingly, we may elect to amend or cancel, from time to time, one or more of our arrangements with third parties, subject to any applicable accrued liabilities and fees. Alternatively, the other parties to such arrangements may, in certain circumstances, be entitled to terminate the arrangements. Further, the amounts payable under certain of our arrangements may depend on the number of products or indications for which any particular technology licensed under such arrangement is used by us. Thus, any statement of potential fees payable by us under each agreement is subject to a high degree of potential variation from the amounts indicated.

Although we or our licensors may file and prosecute patent applications related to various technologies under license or development, or seek to protect some technologies in other ways such as through the maintenance of trade secrets, our product candidates are based on complex and rapidly evolving technologies, and none of our biologic product candidates have completed clinical development. There are also a number of additional uncertainties affecting our ability to materially rely on any of our intellectual property rights as described below under Risks Related to Our Intellectual Property and Potential Litigation. There can be no assurance that any intellectual property assets, or other approaches to marketing exclusivity or priority, would be sufficient to protect our commercialization opportunities, nor that our planned commercialization activities will not infringe any intellectual property rights held or developed by third parties.

Employees

As of December 31, 2012 we employed 24 employees (which includes 9 employees who are employed by To Go Brands, Inc.). We do not expect to hire additional employees during the next 12 months while our products and product candidates advance. Our employees are not represented by a collective bargaining agreement and we have not experienced any work stoppages as a result of labor disputes. We believe our relationship with our employees is good. We also rely on various consultants and advisors to provide services to us.

Available Information

Our website address is www.cardiumthx.com. We make available, free of charge, through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments

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to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file or furnish such reports to the SEC.

For additional financial information, including financial information about our business, please see the consolidated financial statements and accompanying notes to the consolidated financial statements included under Item 8 of this report.

ITEM 1A. RISK FACTORS

You should carefully review and consider the risks described below, as well as the other information in this report and in other reports and documents we file with the SEC when evaluating our business and future prospects. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties, not presently known to us, or that we currently see as immaterial, may also occur. If any of the following risks or any additional risks and uncertainties actually occur, our business could be materially harmed, and our financial condition, results of operations and future growth prospects could be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or a portion of the value of your investment in our stock. You should not draw any inference as to the magnitude of any particular risk from its position in the following discussion.

Risks Related to Our Business and Industry

Our products and product candidates are subject to ongoing regulatory requirements or require regulatory approvals, and in some cases additional prior development or testing, before marketing. We may be unable to develop, obtain or maintain regulatory approval or market any of our product candidates or expand the market of our existing products and technology. If our product candidates are delayed or fail, we will not be able to generate revenues and cash flows from operations, and we may have to curtail or cease our operations.

Our Excellagen® collagen-based product and other wound care and biologics products, as well as our nutraceuticals, dietary supplements and other products within our Cardium Health Sciences Platform, are subject to numerous rules and regulations promulgated by the FDA and other food and health regulatory authorities, including regulations governing the sourcing, manufacture, labeling, handling, storage, marketing and use of such products. In most cases, we will rely on third parties to perform many of these activities, which may not be performed in an effective or timely manner.

Our other product candidates require additional research and development, clinical testing and regulatory clearances before we can market them. To our knowledge, FDA has not yet approved any gene therapy like that contained in our Generx product candidate, or similar product and there can be no assurance that it will. There are many reasons that our products and product candidates may fail or not advance beyond clinical testing, including the possibility that:

- our products and product candidates may be ineffective, unsafe or associated with unacceptable side effects;
- our product candidates may fail to receive necessary regulatory approvals or otherwise fail to meet applicable regulatory standards;
- our product candidates may be too expensive to develop, manufacture or market;
- physicians, patients, third-party payers or the medical community in general may not accept or use our products;
- our potential collaborators may withdraw support for or otherwise impair the development and commercialization of our products or product candidates;

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other parties may hold or acquire proprietary rights that could prevent us or our potential collaborators from developing or marketing our products or product candidates; or

others may develop equivalent, superior or less expensive products.